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(पहला पुनरीक्षण)

Catheter, Foley's Rubber, for Prolonged Urinary Drainage — Specification

(First Revision)

ICS 11.040.40

भारतीय मानक ब्यूरो
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Surgical Instruments Sectional Committee, MHD 01

FOREWORD

This Indian Standard (First Revision) was adopted by the Bureau of Indian Standards, after the draft finalized by the Surgical Instruments Sectional Committee had been approved by the Medical Equipment and Hospital Planning Division Council.

This standard was first published in 1985. In this standard the following modifications have been incorporated:

a) Catheter is made for single use only;
b) Reference clause added;
c) Certain dimensional modification has been done especially for length of catheter;
d) Teat should be non-detachable; and
e) Test method for determining the strength of the catheter (*see* Annex A) and balloon security added (*see* Annex E).

Assistance has been derived from DIN/EN1616 'Sterile urethral catheters for single use (includes Amendment A1 : 1999)', issued by, Deutsches Institute für Normung (DIN).

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values (*revised*)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Indian Standard

CATHETER, FOLEY'S RUBBER, FOR PROLONGED URINARY DRAINAGE — SPECIFICATION

(First Revision)

1 SCOPE

This standard prescribes dimensional and other requirements for foley's catheter used for prolonged urinary drainage, for single use only.

2 REFERENCES

The following standards contains provisions, which through reference in this text, constitutes provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below:

IS No.	*Title*
264 : 2005	Nitric acid — Specification (*third revision*)
323 : 2009	Rectified spirit for industrial use — Specification (*second revision*)
4161 : 1967	Specification for nessler cylinders
4905 : 1968	Methods of random sampling
5430 : 1981	Specification for ammonia preserved concentrated natural rubber latex (*first revision*)
10150 : 1981	Guide for sterilization of medical products

3 SHAPE AND DIMENSIONS

As shown in Fig. 1, read with Table 1.

4 MATERIAL

4.1 Catheter shall be made from rubber latex conforming to IS 5430 and compounded and vulcanized to meet the requirement of this specification.

4.1.1 The natural rubber shall be reasonably free from substances known to have deleterious action on rubber. The composition shall be free from irritants and have no known injurious effect on persons with whom it may come in contact. It shall not react with body fluids and urine.

4.2 A firm thickened bluntly tapering cushion shall be provided at the tip.

4.3 A silicon coating shall be provided to the rubber in order to avoid urethral reactions.

5 WORKMANSHIP AND FINISH

5.1 The catheter shall be homogeneous in composition, adequately vulcanized, evenly and smoothly finished and shall be free from pinholes, pits, cracks, crevices, grooves and other defects. The distal end of the eye shall have smooth finish and shall be entirely free from projections, grit and embedded particles.

5.2 Balloon channel walls shall not stick together hampering inflation or deflation.

5.3 At the external broader end, the catheter shall be firmer, its wall resilient and thicker. This helps prevent collapse of wall during negative syringe suction to relieve blockade by gravel or blood clots.

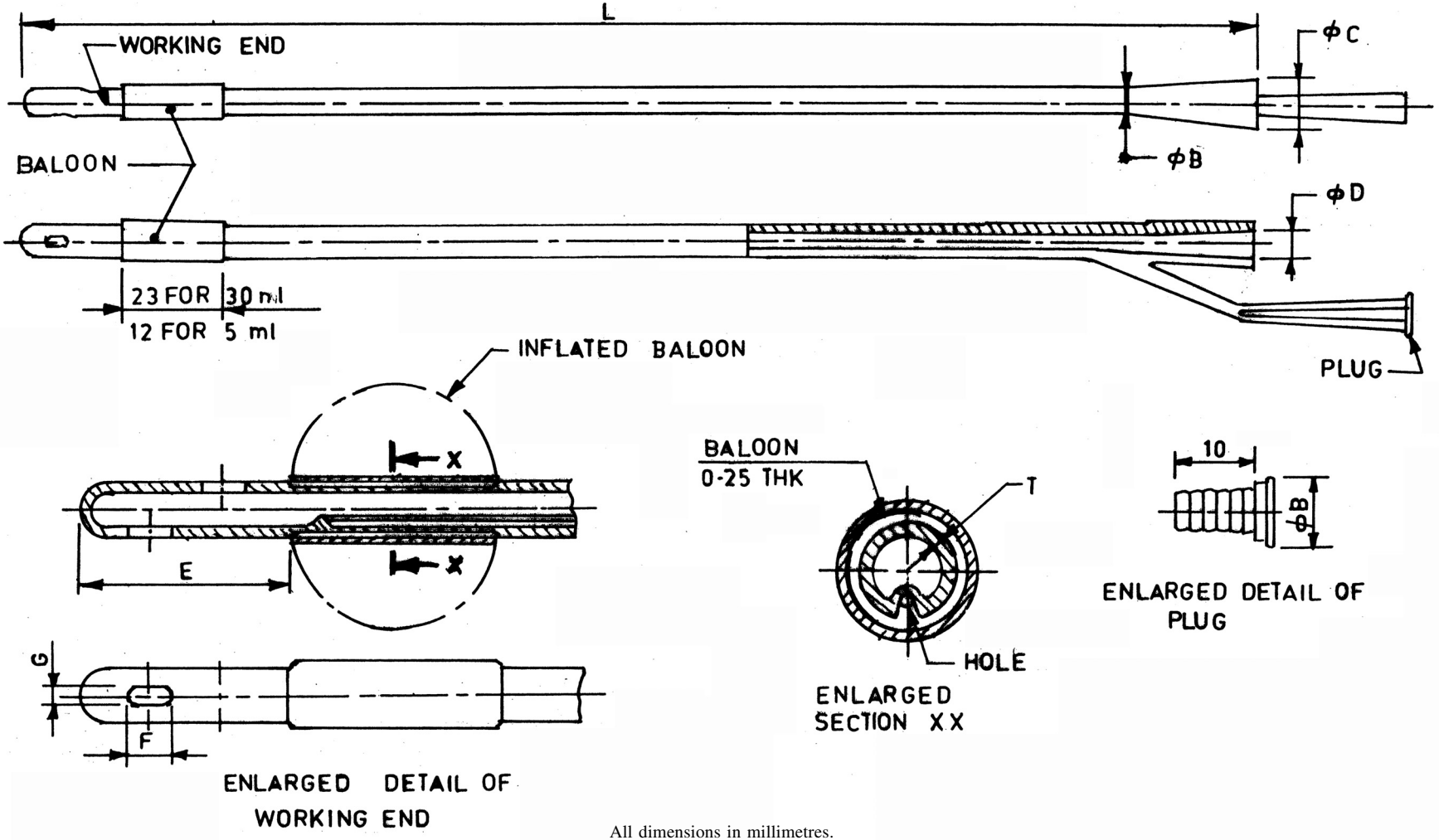
5.4 There shall be colour coding marking on outer end of side (balloon) tube of catheter to identify size at a glance. For the sizes 14 to 24, 30 ml balloon shall represent an average inflation capacity to allow for 20 ml extra water inflation without breaking. Similarly for the sizes 8 to 12, 5 ml balloon shall allow for a total of 10 ml inflation.

5.5 Balloon catheter joint shall be incorporated within catheter substance so as not to affect out side smoothness of catheter and also to permit strengthening effect on balloon wall upon inflation.

5.6 The body of catheter shall be firm, elastic, resilient, able to withstand continuous traction of 1 kg without undue permanent lengthening effect produced after such use for 3 weeks as given in Annex A.

5.7 The catheter side lumen tube leading to the balloon shall have a teat like thickening at its end away from balloon with depression in it adapted to take in a nozzle of 10 or 50 ml glass syringe. The teat should be non-detachable.

5.8 A non-return valve mechanism shall be provided



All dimensions in millimetres.

FIG. 1 CATHER, FOLEY'S PATTERN

to ensure that only if a syringe nozzle is re-applied firmly the teat in the above manner, fluid flows back into the barrel resulting in deflation of balloon for catheter removal.

6 REQUIREMENTS

6.1 Physical Requirements

The physical requirements of rubber used for catheter shall be as given in Table 2.

6.1.1 The catheter shall be free from harmful contamination of heavy metals, arsenic, copper and manganese. The concentration of the metal impurities shall not exceed 5 ppm in the sterile pyrogen free isotonic saline solution as prescribed in Annex D.

6.2 Resistance to Ageing Under Tension

Tubing cut from the catheter when subjected to accelerate ageing under as prescribed in **6.2.1** shall not show any signs of cracking or other evidence of failure of the stretched part.

6.2.1 Cut end of a piece of tubing of the catheter shall be fitted over a glass tube of external diameter 40 to 50 percent greater than the internal diameter of the rubber tubing and the hole subjected to accelerated ageing for 168 h at 70 ± 1°C. There shall be no deterioration in its condition after the test.

6.3 Balloon Security

When tested in accordance with the method given in Annex E, the balloon shall not leak and shall not

Table 1 Critical Dimensions and Ballon Capacities of Foley's Catheter
(*Clause* 3)

All dimensions in millimetres.

		Catheter Size in Charriere Scale[1)]								
		8	10	12	14	16	18	20	22	24
Length, (*L*) ± 5		300	300	400	400	400	400	400	400	400
Wall Thickness (*T*)		0.3 ±0 .05	0.3 ±0.05	1.0±0.1	1.0± 0.1	1.0±0.1	1.0± 0.1	1.0±0.1	1.0±0.1	1.0±0.1
Balloon Capacity, millilitre		5 ± 0.5	5 ± 0.5	5 ± 0.5	30 ± 1	30 ± 1	30 ± 1	30 ± 1	30 ± 1	30 ± 1
Average Flow Rate Minimum ml/min	Drainage lumen	15	30	50	70	100	100	100	100	100
	Irrigation lumen	n.a[2)]	n.a	n.a	25	25	25	25	30	30
B ± 0.5		5.0	5.5	6.0	6.5	7.0	7.5	8.5	9.0	9.5
C ± 0.5		7.5	8.0	8.5	9.0	9.5	10.0	11.0	11.5	12.0
D ± 0.5		4.5	5.0	5.5	6.0	6.5	7.5	8.0	8.5	9.0
E ± 1.0		15.0	15.0	15.0	30.0	30.0	30.0	30.0	30.0	30.0
F ± 0.5		3.0	3.0	3.0	6.0	6.0	6.0	6.0	6.0	6.0
G ± 0.3		1.5	1.5	1.5	3.0	3.0	3.0	3.0	3.0	3.0

[1)] Charriere scale = 1/3 mm.
[2)] n.a = not applicable.

Table 2 Physical Requirements of Rubber Used for Catheters
(*Clause* 6.1)

Sl No.	**Characteristic**	**Value Before Ageing**	**Maximum Change from the Original Value after Accelerated Ageing at 70 ±1°C for 168 h in Air Oven**
(1)	(2)	(3)	(4)
i)	Tensile strength, MN/m² (kgf/cm²), *Min*	10 (100, approximately)	
ii)	Elongation at break, percent, *Min*	400	$^{+10}_{-25}$ percent
iii)	Percent elongation under a tensile stress of 2 800 kN/m² (28 kgf/cm² approximately) of original area of cross-section of test piece	Between 100 and 250	—
iv)	Tension set (at 200 percent elongation), percent, *Max*	10	—
v)	*p*H of water extract	7 ± 0.5 (*see* Annex B)	—
vi)	Extractable colour	No colour or precipitate shall beformed but faint turbidity (to the extent of slight translucence) may be permitted (*see* Annex C)	—

occlude the drainage eyes.

NOTE — The change in profile at each end of the uninflated balloon should be smoothly blended with the shaft. The balloon should be capableof approximately symmetrical expansion when filled with water at ambient temperature to its specified balloon capacity.

6.4 Flow Rate

The minimum flow rate shall be as given in Table 1.

7 STERILIZATION

The cartons containing the catheters shall be sterilized by ETO sterilization or radiation sterilization in accordance with the procedures given in IS 10150. Suitable indicators shall be affixed to each pack for indication of the sterility.

8 SAMPLING

Sampling procedure and acceptance criteria for the instruments shall be as agreed to between the purchaser and the supplier. However, a recommended scheme for the same is given in Annex F.

9 MARKING

9.1 Each catheter shall be legibly and indelibly marked with the manufacturer's name or recognized trade-mark, if any, and the year of manufacture together with the size number and balloon capacity.

9.2 BIS Certification Marking

The product may also be marked with the Standard Mark.

9.2.1 The use of the Standard Mark is governed by the provisions of the *Bureau of Indian Standards Act*, 1986 and the Rules and Regulations made thereunder. The details of conditions, under which the license for the use of the Standard Mark may be granted to manufactures or producers, may be obtained from the Bureau of Indian Standards.

10 PACKING

10.1 Each catheter shall be doubled packed in a bag leak proof for sterilization. Ten such bags shall be packed in a bag which is leak proof for sterilization purpose. The bags may then be packed in cartons.

10.2 The package shall be legibly and indelibly with the name or trade-mark of the manufacturer, lot and serial number of the package, size number of the catheter, month and year of manufacturer, and number of catheters in the package.

ANNEX A
(*Clause* 5.6)

TEST METHOD FOR DETERMINING THE STRENGTH OF THE CATHETER

A-1 PRINCIPLE

Catheters fitted with balloons may be *in-situ* for prolonged periods. Such catheters are therefore immersed for 14 days in simulated urine prior to testing. This step is omitted for catheters without balloons. A tensile force is applied to the union of the tip and shaft of the catheter. For catheters with lateral eyes, the tensile force is to be applied to the eyes.

For catheters with no lateral eyes, the tensile force is applied between the shaft of the catheter and the drainage funnel. On removal of this force, the catheter is examined for signs of failure**.**

A-2 REAGENTS

Simulated urine, *p*H approximately 6.6 of the following composition, the reagents being of recognized analytical grade:

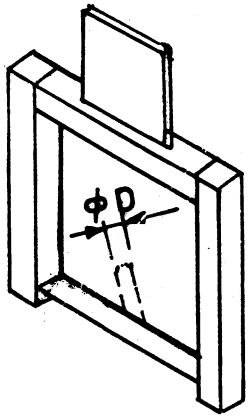
Urea	:	25.0 g
Sodium chloride	:	9.0 g
Disodium dihydrogen orthophosphate, anhydrous	:	2.5 g
Potassium dihydrogen orthophosphate	:	2.5 g
Ammonium chloride	:	3.0 g
Creatinine	:	2.0 g
Sodium sulphite, hydrated	:	3.0 g
Distilled water (for making up to)	:	1.0 l

NOTE — This solution can support microbial growth. There is a strong possibility that large numbers of micro-organisms will be present in the solution at the end of the tests. These procedures should be carried out by trained personnel taking appropriate precautions in the handling of the immersed catheter and the disposal of the contaminated solution.

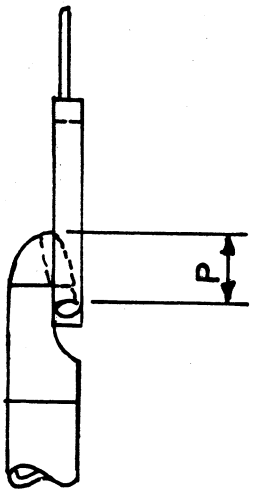
A-3 APPARATUS

A-3.1 Device for suspending catheter with lateral eyes, comprising a pin which passes through a drainage eye of the catheter, the pin having a diameter between 50 percent and 75 percent of that of the drainage lumen of the catheter to be tested. An example of a suitable device is shown in Fig. 2.

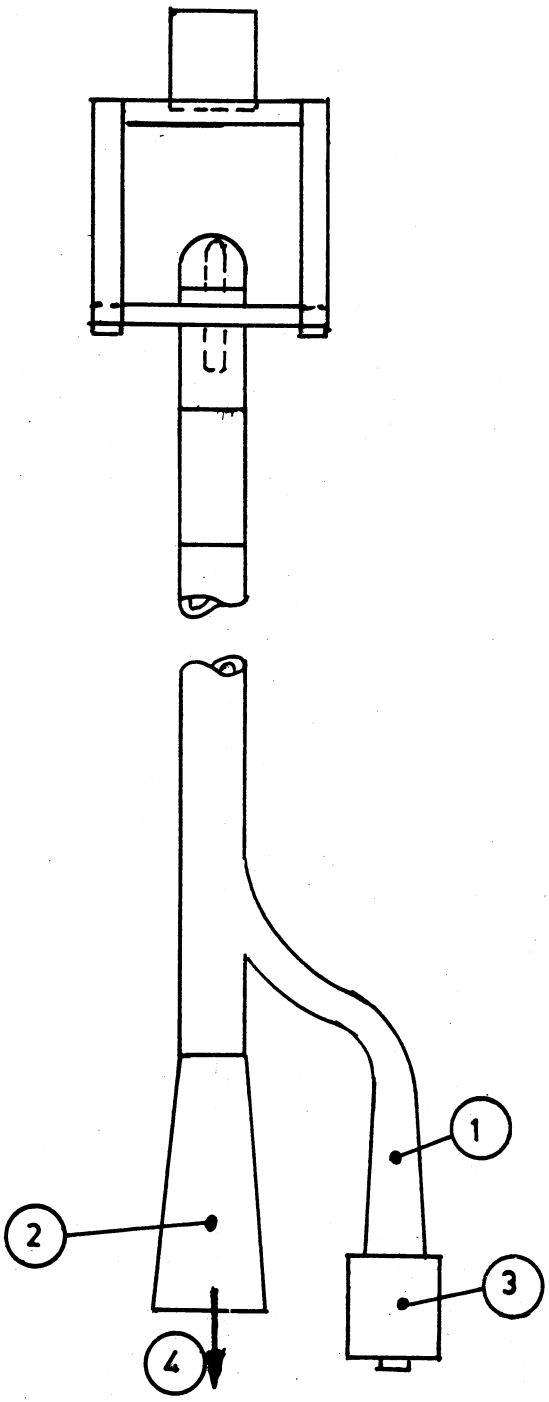
For catheter without lateral eyes, the shaft of the catheter is suspended in a suitable clamp.



a) Example of support frame and pin



b) Pin introduced through eye of catheter



c) Arrangement for testing

NOTES

1 Dimension *D* is between 50 percent and 75 percent of the diameter of the drainage lumen.

2 Dimension *P* is sufficiers to allow the tip of the pin to engage the tip of the catheter and not perms the supporting member to engage the rim of the eye when the catheter is loaded.

1) Inflation pannel
2) Drainage pannel
3) Value
4) Direction of test force

FIG. 2 APPARATUS AND GENERAL ARRANGEMENT FOR TESTING CATHETERS STRENGTH

A-3.2 Device for attaching a weight to the drainage funnel and a weight, their combined mass being 1 kg for catheters of outside diameter greater than 3.3 mm and 0.75 kg for catheters up to guage size 3.3 mm.

A-3.3 Water bath or other device, capable of being controlled at 37 ± 2°C.

A-3.4 Stopwatch

A-4 PROCEDURE

Immerse the catheter in the freshly prepared simulated urine (*see* **A-2**) in water bath (*see* **A-3.3**) controlled at 37 ± 2 °C, so that the balloon and shaft are completely submerged.

Allow the catheter to remain in the simulated urine for 14 days and then remove the catheter, rinse it with tap water and dry it. Allow the catheter to come to a temperature of 23 ± 2 °C.

Suspend the catheter from the suspension device (*see* **A-3.2**). Attach the weight to the drainage funnel of the catheter. Gently lower the weight until it is freely suspended from the catheter. Allow it to remain in this position for 1 min.

Remove the weight and visually examine all unions of the catheter for detachment or failure of bonds and any eyes for signs of splitting.

A-5 TEST REPORT

The test report shall contain the following information:

a) Identity of the catheter; and
b) Condition of the dip/shaft union and eyes after testing.

ANNEX B
(*Table* 2)

DETERMINATION OF *p*H OF WATER EXTRACT

B-1 PROCEDURE

Cut 5 catheters into 2 mm pieces. Autoclave the pieces for 5 min at a pressure of 40 to 50 kN/m^2 (approximately 0.4 to 0 5 kgf/cm^2) with 200 ml of water. Discard the first extract and repeat the process with another 500 ml of water for 40 min. Decant the extract, cool and determine the *p*H meter.

ANNEX C
(*Table* 2)

TEST FOR EXTRACTABLE COLOIUR

C-1 PROCEDURE

Cut 5 catheters into 10 mm pieces and mix them. Weigh about 20 g of these pieces. Autoclave them with 100 ml of water under a steam pressure of 100 of 135 kN/m^2 (approximately 1.0 to 1.35 kgf/cm^2) at a temperature of 120°C to 125°C for 30 min. Cool and examine the extracted solution.

ANNEX D
(*Clause* 6.1.1)

TEST FOR HEAVY METALS

D-0 OUTLINE OF THE METHOD

D-0.1 The solution is prepared as in **D-0.2** and tested with aqueous hydrogen sulphide solution. The resultant brown colour, if any, is matched with that produced with a standard lead solution.

D-0.2 Preparation of Test Solution

Pass 40 ml portions of sterile pyrogen-free isotonic saline solution containing 9 g of sodium chloride per litre at room temperature through the catheter at a low rate of approximately 10 ml/min and collect the effluent. Make up the solution to 50 ml.

D-1 APPARATUS

D-1.1 Nessler Cylinders — 100 ml capacity (*see* IS 4161).

D-2 REAGENTS

D-2.1 Citric Acid

D-2.2 Concentrated Nitric/Acid — *see* IS 264.

D-2.3 Bromophenol Blue Indicator — Dissolve 0.1 g of bromophenol blue in 100 ml of rectified spirit conforming to IS 323.

D-2.4 Coppier Sulphate

D-2.5 Hydrogen Sulphide Gas, from Kipp's apparatus.

D- 2.6 Dilute Nitric Acid, approximately 1 percent.

D-2.7 Ammonium Hydroxide — Dilute 1 volume of liquor ammonia (r.d. 0.92) with 10 volumes of water.

D-2.8 Thymol Blue Indicator — Dissolve 0.1 g of thymol blue in 100 ml of rectified spirit conforming to IS 323.

D-2.9 Potassium Cyanide Solution — 10 percent (*m*/*v*).

D-2.10 Hydrogen Sulphide Solution — Freshly prepared saturated solution.

D-2.11 Standard Lead Solution

Dissolve 0.800 g of lead nitrate in water and make up the solution to exactly 1 000 ml. Pipette out 10 ml of the solution and dilute it again with water to 1 000 ml. One millilitre of the final solution contains 0.500 mg of lead (Pb). The solution shall be freshly prepared.

D-3 PROCEDURE

D-3.1 Prepare a solution as in **D-0.2** but make up the volume to 100 ml. Transfer the solution to a beaker, Add 5 g of citric acid and adjust *p*H from 3.0 to 3.4 by adding ammonium hydroxide to give a yellowish purple colour with bromophenol blue indicator. Add about 5 g of copper sulphate to act as co-precipitant, Precipitate sulphides by passing hydrogen sulphide until solution is saturated. Dissolve the sulphides, without previous washing, with 5 ml of hot dilute nitric acid, drawing solution through filter into the original flask; wash with hot water, and collect the washing along with the solution in nitric acid. Boil to remove sulphurated hydrogen. Concentrate the content to about 75 ml. Add 3 to 4 g of concentrated nitric acid previously dissolved in water, make ammoniacal to bring *p*H between 8.5 and 10 (bluish-green to blue towards drop of thymol blue indicator) and add 5 ml of potassium cyanide solution. Transfer to a Nessler cylinder, add 10 ml of hydrogen sulphide solution, dilute to the mark and shake. Carry out a control test using 1 ml of standard lead solution and the same quantities of other reagents as used in test with the material.

D-3.2 The test solution shall be taken as not having exceeded the limit prescribed, if the intensity of colour produced in the test with the material is not greater than that produced in the control test.

ANNEX E

(*Clause* 6.3)

TEST METHOD FOR DETERMINING BALLOON SECURITY

E-1 PRINCIPLE

The catheter balloon is inflated with water to the manufacturer's maximum stated capacity and immersed for 14 days in stimulated urine. A tensile force is applied to the catheter and the catheter examined visually for occlusion of the drainage eyes, if present, by the balloon and leakage from the balloon.

E-2 REAGENTS

E-2.1 Distilled Water

E-2.2 Stimulated Urine, of composition as given in **A-2**.

E-3 APPARATUS

E-3.1 Device for suspending the catheter, consisting

of a plate of rigid material, having the following constructional features:

a) A hole of diameter of 1 mm greater than that of the nominal size of the catheter under test, with a countersink on the upper surface of the plate.
b) A countersink of 90° included angle of sufficient size to support the base of the balloon of the catheter under test.
c) No sharp edges at the junction of the hole and the countersink.

E-3.2 Water bath, or other device capable of being controlled at 37 ± 2 °C.

E-3.3 Device for attaching a weight to the drainage funnel or shaft of the catheter, and a series of weights, the combined masses of the attachment (*see* Table 3).

Table 3 Requirements for Load Test
(*Clause* E-3.3)

Sl No.	Designated Size		Mass
	Outside Diameter mm	Charriere Equivalent[1)] FG/Ch/Fr	kg
(1)	(2)	(3)	(4)
i)	2.7 or less	8 or less	0.3
ii)	3.3	10	0.45
iii)	4.0	12	0.6
iv)	4.7	14	0.7
v)	5.3 to 10	16 to 30	1.0

[1)] The Charriere equivalent is given for information.

E-3.4 Stopwatch

E-4 PROCEDURE

Inflate the catheter balloon with distilled water to manufacturer's maximum stated balloon capacity.

Immerse the catheter in the freshly prepared simulated urine (*see* **E-2.2**) in the water bath (*see* **E-3.2**) controlled at 37 ± 2 °C, so that the tip and the balloon are completely submerged.

Allow the catheter to remain in the simulated urine for 14 days, then remove the catheter, rinse it with tap water, and dry it. Allow the catheter and contents to come to a temperature of 23 ± 2 °C.

Place the catheter in the suspension device (*see* **E-3.1**), with the tip uppermost, the balloon resting in the countersink and the shaft protruding from the hole.

Select the weight (*see* **E-3.3**) appropriate to the catheter under test, as given in Table 3.

Manually support the weight. Attach the weight to the shaft or drainage funnel of the catheter and gently lower the weight until it is freely suspended from the catheter. Allow it to remain in this position for 1 min.

With the weight in position, visually examine the catheter at the end of a 1 min period for,

a) occlusion of the drainage eyes, if present, by the balloon; and
b) leakage of water from the balloon.

NOTES

1 To facilitate placement of the catheter under test, the plate can comprise two halves, symmetrical about the center line of the hole.

2 To facilitate placement of the catheter in a single piece suspension device, it may be necessary either to remove the funnels, having first ligatured the catheter shaft, or to drain the balloon, introduce the catheter and then reinflate the balloon.

E-5 TEST REPORT

The test report shall contain the following information:

a) Identity of the catheter;
b) Whether the drainage eyes were occluded by the balloon; and
c) Whether leakage from the balloon was observed.

ANNEX F
(*Clause* 8)
SAMPLING PLAN AND CRITERIA FOR CONFORMITY

F-1 LOT

In a consignment, all the catheters of the same size number, manufactured from the same material under similar conditions shall be grouped together to constitute a lot.

F-2 SCALE OF SAMPLING

F-2.1 Each lot shall be tested separately for the requirements of this specification.

F-2.2 The number of catheters to be sampled from each lot for examining the requirements of shape and

dimensions, material and workmanship and finish shall be in accordance with Table 4. These samples shall be selected at random with the use of random number tables (*see* IS 4905).

Table 4 Scale of Sampling for Catheters
(*Clause* F-2.2)

Sl No.	Lot Size	Sample Size for Testing the Requirements of 3, 4 and 5
(1)	(2)	(3)
i)	Up to 25	5
ii)	25 - 50	8
iii)	51 - 150	13
iv)	151 - 300	20
v)	301 and above	32

F-3 NUMBER OF TESTS AND CRITERIA FOR CONFORMITY

F-3.1 When the catheters are packed in cartons, at least two cartons shall be opened for selecting the required number of items. After sampling, the cartons as well as the bags shall be re-packed in accordance with the requirements given in **7** and **8**.

F-3.2 Each catheter selected according to Table 4 shall be examined for the shape and dimensions, material and workmanship and finish. Any catheter failing in one or more of these requirements shall be considered to be defective. No defective catheter shall be permitted, if the lot is to be deemed acceptable under this clause.

F-3.3 The lot which has been found satisfactory under **F-3.2** shall then be tested for other requirements, For this purpose, three samples shall be drawn for hydraulic test, one for physical requirements, and one for resistance to ageing under tension. If found suitable, the samples already used for one test may be used for other test also. All the samples tested for various characteristics shall meet the corresponding requirements, if the lot is to be accepted under this clause.

Bureau of Indian Standards

BIS is a statutory institution established under the *Bureau of Indian Standards Act*, 1986 to promote harmonious development of the activities of standardization, marking and quality certification of goods and attending to connected matters in the country.

Review of Indian Standards

Amendments are issued to standards as the need arises on the basis of comments. Standards are also reviewed periodically; a standard along with amendments is reaffirmed when such review indicates that no changes are needed; if the review indicates that changes are needed, it is taken up for revision. Users of Indian Standards should ascertain that they are in possession of the latest amendments or edition by referring to the latest issue of 'BIS Catalogue' and 'Standards : Monthly Additions'.

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